

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection on 26 March 2010. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed 26 March 2010 has been entered, wherein no claims were amended or cancelled but arguments traversing the rejections of record were presented. Claims 27, 32, 37, and 42 remain in the application and are examined herein.

Double Patenting: Non-Statutory

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. **A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s).** See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27, 32, 37, and 42 remain rejected for reasons of record under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2 and 8-11 of **US 5,371,017**. Applicant's argument at page 3 of the Remarks filed 26 March 2010 have been fully considered but they are not persuasive. Applicant traverses the rejection of record as having been improperly based on teachings of the patent specification rather than the descriptions of the patented claims, asserting that only the patent claims, and not the teachings of the patent specification, can be the proper basis for stating a rejection for obviousness-type double patenting. It is agreed that statements in the rejection of record to which Applicant points were unnecessary. The patented claims 2 and 8-11 state:

Art Unit: 1656

2. An isolated [polynucleotide] composition of claim 1, wherein said polynucleotide encodes the HCV protease of FIG. 1.
8. An expression vector for producing Hepatitis C virus (HCV) protease in a host cell, which vector comprises: a polynucleotide encoding HCV protease; transcriptional and translational regulatory sequences functional in said host cell operably linked to said HCV protease-encoding polynucleotide; and a selectable marker.
9. The vector of claim 8, which further comprises a sequence encoding a fusion partner, linked to said Hepatitis C virus protease-encoding polynucleotide to form a fusion protein upon expression.
10. The vector of claim 9, wherein said fusion partner is selected from the group consisting of hSOD, yeast α -factor, IL-2S, ubiquitin, β -galactosidase, β -lactamase, horseradish peroxidase, glucose oxidase, and urease.
11. The vector of claim 10, wherein said fusion partner is selected from the group consisting of ubiquitin, hSOD, and yeast α -factor.

Claims 27, 32, 37, and 42 herein state:

27. A composition comprising an isolated polynucleotide comprising the sequence of SEQ ID NO:69.
32. A composition comprising an isolated polynucleotide comprising the sequence of SEQ ID NO:85.
37. An expression vector for producing a polypeptide in a host cell, wherein said vector comprises a polynucleotide comprising the sequence of SEQ ID NO:69; transcriptional and translational regulatory sequences functional in said host cell operably linked to said polynucleotide; and a selectable marker.
42. The expression vector of claim 37 wherein said nucleotide further comprises the sequence of SEQ ID NO:85.

Applicant does not dispute that Figure 1 of both the patent and the instant application discloses the same 2064-nucleotide coding sequence depicted in SEQ ID NO:69 of the pending claim 27. A polynucleotide composition comprising a polynucleotide encoding the amino acid sequence set forth in FIG. 1 is thus a composition of the pending claim 27 that comprises an isolated polynucleotide comprising the nucleic acid sequence of SEQ ID NO:69. While the scope of the patented claim 2 may be broader than that of pending claim 27, a composition of the pending claim 27 is clearly also a composition of the patented claim 2. Double patenting results when the right to exclude granted by a first patent is unjustly extended by the grant of a later issued patent or patents. *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982). The rejection of record with respect to claim 27 is maintained until and unless an effective terminal disclaimer is filed.

Applicant does not dispute that an expression vector of the patented claim 8 is itself a composition of matter – a polynucleotide – that within **comprises** a polynucleotide region encoding an HCV protease together with transcriptional and translational regulatory sequences functional in the host cell that are operably linked to the HCV protease-encoding polynucleotide and that further comprises a region encoding a selectable marker, and that such a vector composition may further comprise, according to the patented claims 9-11, a region encoding a fusion partner that is a portion of a human superoxide dismutase amino acid sequence. Neither does Applicant dispute that SEQ ID NO:85 of claim 32 herein is polynucleotide that is a portion of the vector construct cflSOD600 described in both the patent and the pending application that encodes a fusion polypeptide comprising a portion of a human superoxide dismutase amino acid sequence fused to the polypeptide encoded by SEQ ID NO:69 herein, thus a composition of the pending claim 32 may be a composition of the patented claims 9-11 and, indeed, the pending claims 37 and 42 are drawn to compositions having more particular descriptions of the components within vectors of the patented claims 8-11. While the scope of the patented claims 8-12 may be broader than that of the pending claims 32, 37, and 42, a composition of the pending claim 32 may be an expression vector of the patented claim 8 and expression vectors of the pending claims 37 and 42 are clearly also vectors of the patented claims 8-11. Double patenting results when the right to exclude granted by a first patent is unjustly extended by the grant of a later issued patent or patents. *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982). The rejection of record with respect to claims 37 and 42 is maintained until and unless an effective terminal disclaimer is filed.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the

Art Unit: 1656

statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Manjunath Rao, can be reached at 571.272.0939. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

/William W. Moore/
Examiner, Art Unit 1656

/Nashaat T. Nashed/
Primary Examiner, Art Unit 1656